NOV 1 6 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K013101 **"**

Introduction

According to the requirements of 21 CFR 862.1070, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Lab Group
Riobamba 2944
2000 – Rosario - Argentina

Contact person: Viviana Cétola

Date Prepared: July 05, 2001

6-2 Device Name

Proprietary name: WIENER LAB. AMILASA 405 CINETICA

Common name: Amylase test system.

Classification name: Catalytic Methods, Amylase

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed GENZYME DIRECT AMYLASE test system for the serum / plasma application and TRACE AMYLASE DST for the urine application.

6-4 Device Description

Kinetic method.
The principle is based on the following reaction system:

$$10\ CNPG_3 \xrightarrow{\alpha\ \text{amylase}} 9\ CNP + 1\ CNPG_2 + G_3 + G$$

$CNPG_3$ (2-Chloro-4-Nitrophenyl-α-D-Maltotrioside)
CNP can be detected spectrophotometrically at 405 nm.

6-5 Intended Use

The AMILASA 405 CINETICA test system is intended to measure the activity of the enzyme amylase in serum, plasma and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

6-6 Equivalencies and differences

The WIENER LAB. AMILASA 405 CINETICA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed GENZYME DIRECT AMYLASE test system for the serum / plasma application and TRACE AMYLASE DST for the urine application.

The following table illustrates the similarities and differences between the WIENER LAB. AMILASA 405 CINETICA test system and the currently marketed GENZYME DIRECT AMYLASE test system.

	GENZYME Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of amylase in human sera and heparinized plasmas.	Quantitative determination of amylase in human sera, heparinized plasmas and urine.
Test Principle	Kinetic method. The principle is based on the following reaction system: $10\ CNPG_3 \xrightarrow{\alpha\ amylase} 9\ CNP + 1 CNPG_2 + G_3 + G$ CNP can be detected spectrophotometrically at 405 nm	
Essential Components	$CNPG_3$ (2-Chloro-4-Nitrophenyl-α-D-Maltotrioside) substrate	
Reagents	Single reagent	R1: $CNPG_3$ Substrate R2: MES Buffer
Precautions and Warnings	Do not pipette by mouth. Avoid contamination of the reagent with salivary α amylase	
Preparation of Working Reagent	Ready to use	Dissolution of R1 with R2

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	GENZYME Test System	WIENER LAB. Test System
Storage and Stability of Working Reagent	Unopened reagent is stable until expiration date printed on the label when stored at 2-8ºC. After opening, the reagent is stable for 60 days when properly capped immediately after each opening and stored at 2-8ºC.	Unopened reagents are stable until expiration date printed on the labels when stored at 2-8ºC. After preparation the reagent is stable for 15 days at room temperature or 60 days at 2-10ºC.
Instability or deterioration of reagents	Reagent Blank Absorbance > 0.500. Inability to recover control values. Extreme turbidity.	
Working Temperature Range	37ºC	25 - 37ºC
Wavelength of reading.	405 nm	
Linearity	2000 U/l	1000 U/l
Minimum detection limit	1.0 U/l (theoretical)	4.7 U/l (real)
Expected values	25 - 94 U/l	Until 125 U/l
Intra-assay precision	Normal Control: CV = 4.6 % Abnormal Control: CV = 3.3 %	Normal Control: CV = 3.48 % Abnormal Serum Control: CV = 1.51 %
Inter-assay precision	Normal Control: CV = 6.1 % Abnormal Control: CV = 4.2 %	Normal Control: CV = 5.53 % Abnormal Control: CV = 1.95 %

The following table illustrates the similarities and differences between the WIENER LAB. AMILASA 405 CINETICA test system and the currently marketed TRACE AMYLASE DST test system.

	TRACE Test System	**WIENER LAB. Test System**
Intended Use	Quantitative determination of amylase in human sera and urine	Quantitative determination of amylase in human sera, plasma and urine.
Test Principle	Kinetic method. The principle is based on the following reaction system: 5 $EpNPG_7$ + 5 H_2O ↓ α amylase, α glucosidase 5 p-nitrophenol + 14 Glucose pNP can be detected spectrophotometrically at 405 nm	Kinetic method. The principle is based on the following reaction system: 10 $CNPG_3$ ↓ α amylase 9 CNP+1$CNPG_2$ + G_3 + Glucose CNP can be detected spectrophotometrically at 405 nm
Essential Components	$EpNPG_7$ (Ethylidene-pNP-G_7) substrate α glucosidase.	$CNPG_3$ (2-Chloro-4-Nitrophenyl-α-D-Maltotrioside) substrate.
Reagents	Single reagent	R1: $CNPG_3$ Substrate R2: Buffer
Precautions and Warnings	Do not pipette by mouth. Avoid contamination of the reagent with salivary α amylase	

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	TRACE Test System	WIENER LAB. Test System
Preparation of Working Reagent	Ready to use	Dissolution of R1 with R2
Storage and Stability of Working Reagent	Unopened reagent is stable until expiration date printed on the label when stored at 2-8ºC. After opening, the reagent is stable until expiry when properly capped immediately after each opening and stored at 2-8ºC.	Unopened reagents are stable until expiration date printed on the labels when stored at 2-8ºC. After preparation the reagent is stable for 15 days at room temperature or 60 days at 2-10ºC.
Instability or deterioration of reagents	Reagent Blank Absorbance > 0.500. Inability to recover control values. Extreme turbidity.	
Sample	Human serum and urine.	Human serum, plasma and urine.
Working Temperature Range	30 / 37ºC	25 / 30 / 37ºC
Wavelength of reading.	405 nm	
Linearity	2000 U/l	1000 U/l
Expected values	Serum: 35 – 140 U/l (37ºC) Urine: 1 – 17 U/hour	Serum: until 125 U/l (37ºC) Random urine: until 680 U/l

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	TRACE Test System	WIENER LAB. Test System
Intra-assay precision	Normal Control: CV = 5.3 % Abnormal Control: CV = 0.9 %	Normal Control: CV = 3.59 % Abnormal Control: CV = 1.49 %
Inter-assay precision	Normal Control: CV = 8.1 % Abnormal Control: CV = 2.6 %	Normal Control: CV = 5.53 % Abnormal Control: CV = 1.95 %

6-7 Conclusion Based on the data above mentioned, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Viviana Cétola
QC/QA Manager
Wiener Laboratorios S.A.I.C.
2944 Riobamba
Rosario, Santa Fe
Argentina

NOV 1 6 2001

Re: K013101
Trade/Device Name: Wiener Lab. Amilasa 405 Cinética
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase Test System
Regulatory Class: II
Product Code: JFJ
Dated: August 15, 2001
Received: September 17, 2001

Dear Dr. Cétola:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013101

510(k) Number (if known): K013101

Device Name: Wiener lab.
Amilasa 405 cinética

NOV 1 6 2001

Indications For Use:

The "Wiener lab. Amilasa 405 cinética" test system is a quantitative in vitro diagnostic device intended to measure the activity of the enzyme amylase in serum, plasma and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division S
Division of vices
510(k) Num K013101

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

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